

REMARKS

Review and reconsideration of the non-final Office Action mailed February 25, 2008 (hereinafter "Office Action"), is hereby requested in view of the following remarks. At the time of the Office Action, claims 1-11 and 13-21 were pending. By this Amendment, claims 1, 6, 11, 18, 19 and 21 are amended. No new matter is added.

Claim Objections

In the Office Action, claims 1-11 and 13-21 were objected to because plasticizer was spelled incorrectly in claims 1, 6, 11, 18, 19 and 21. Claims 1, 6, 11, 18, 19 and 21 are amended to correct this spelling error. In addition, claims 1 and 21 have been amended to recite "a seamless shell surrounding this core." The seamless limitation was previously present in claim 1. No new matter is added.

Claim Rejections -35 U.S.C. § 103(a)

In the Office Action, claims 1, 5-6, 11-12 and 18-19 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2005/0100640 filed by Pearce (hereinafter "Pearce") in view of U.S. Patent No. 5,286,496 issued to Stapler *et al.* (hereinafter "Stapler").

Prior to addressing the cited references, Applicants wish to review the claimed invention. As set forth in amended claim 1, the claimed spherical coated capsule is drawn to:

1. (currently amended) A spherical coated capsule comprising
 - (a) a liquid or viscous core,
 - (b) a seamless shell surrounding this core, and
 - (c) a seamless, solid coating on said shell, wherein
 - the diameter of the coated capsule is in the range of 5 - 9 mm,
 - the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule,
 - the diameter of the shell is in the range of 3 - 7 mm,
 - the thickness of the shell is in the range of 20 -200 μ m,
 - the ratio of shell thickness to shell diameter is in the range of 0.004:1 - 0.04:1 ,
 - the shell contains 70 - 90 % (m/m) gelatine or alginate and 10 - 30 % (m/m) plasticizer ~~plasticiser~~, based on the solids content

of said shell, and

- the core has a flavouring content in the range of 1 - 100 % (m/m), based on the total mass of the core, wherein the plasticizer ~~plasticiser~~ is selected from the group that consists of glycerol, propylene glycol, sorbitol, maltitol, and combinations thereof.

Of particular interest, the claimed spherical coated capsule includes "a seamless, solid coating on said shell, wherein ... the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule." In addition, the claimed microcapsules made by the claimed process provide substantial benefits of the prior art. As explained in the specification, prior to the claimed invention, "it has been found to be disadvantageous that the majority of shells of ready-to-consume capsules available commercially are detectable as an unpleasant, rubbery, tough residue. Corresponding observations are made and found to be particularly negative especially in the case of larger filled capsules with diameter of about 4 mm," *see* Specification, paragraph [0005], subheading 1. In contrast to the prior art materials, the claimed spherical coated capsules (a) do not have a disturbing haptic effect, (b) dissolve rapidly, and (c) are not sticky or tacky. The core liquid containing flavoring that is to be released or is released should give rise to a sensory effect with a substantial impact in the mouth, *see* Specification, paragraph [0005], subheading 2.

Turning now to the instant rejection and the Pearce reference entitled "Microcapsule Edibles." The Office Action asserts that the seamless shell and coating elements are disclosed by the statement that the films disclosed in Pearce can be "made whole around a liquid center" (Pearce, paragraph [0103]) and that the film layers can be "laminated, bonded or lain together" (Pearce, paragraph [0089]-[0090] and Figs. 2 & 3). The Examiner asserts that these layers meet the limitations of the seamless coating and, presumably, the coating composition. Stapler is only relied upon for the disclosure of shell thickness, particle diameter and ratio of thickness to diameter.

Applicants note that Pearce is actually drawn to a variety of uses for flavored, soluble films and tapes, *see* Pearce, Figures 1-19 and accompanying discussion. In fact, Pearce does not mention seamless microcapsules until paragraph [0326] and does not disclose or suggest coating the microcapsule shell with the claimed "seamless, solid coating," much less the claimed seamless, solid coating comprising "at least one sugar or sugar-alcohol in an amount from about 30 – 90 %

(m/m) based on the total mass of the coated capsule." A review of Pearce clearly demonstrates that the methods of making films and their conversion into softgels or two-piece tablets (which was relied upon in the Office Action) is treated separately from the formation of microcapsules, see Pearce, paragraphs [0324]-[0436].

The Office Action relies upon paragraph [0103] for the claim limitation of a seamless coating and a seamless shell. With respect to paragraph [0103] Pearce clarifies that the disclosure that a film can be "made whole around a liquid center" in paragraph [0103] is a reference "softgel technology," see Pearce, paragraph [0325]. Pearce then discloses that softgels can be made by shaping two ribbons of polymer into convex shapes, inserting a liquid, and *welding* the convex shapes into an oblique spheroid, see Pearce, paragraph [0326]. The Office Action interprets the different layers of the film, e.g., layered film ribbons, as meeting the claimed coating limitation. Because the two ribbons of film are welded together, they would not meet the claimed limitations of a seamless shell and a seamless coating. Thus, the cited portion of Pearce is no different than the two-piece capsules, also disclosed in paragraph [0103], that were not cited by the Examiner as disclosing the claimed seamless coating or seamless shell. Thus, Pearce clearly fails to disclose or suggest the claimed limitations of "a seamless, solid coating on said shell, wherein ... the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule."

The Stapler reference also fails to disclose or suggest the claimed limitations of "a seamless, solid coating on said shell, wherein ... the solid coating comprises at least one sugar or sugar-alcohol in an amount from about 30 - 90% (m/m), based on the total mass of the coated capsule." In fact, the previous Office Action mailed August 28, 2008, expressly states that "Stapler does not disclose the microcapsules being coated or gel points of the gelatin and plasticizer," see page 3. As neither Pearce nor Stapler disclose these element of the claimed microcapsule, Applicants respectfully assert that the combination of Pearce and Stapler fails to establish a *prima facie* case of obviousness and respectfully request that rejections based on the combination of Pearce and Stapler be withdrawn.

Applicants note that these arguments do not rely upon either of the current amendments to the claims. Accordingly, Applicants believe that should a notice of allowance not be forthcoming, any forthcoming Office Action should be made non-final.

Another important feature of the claimed invention is the ability to provide a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but also dissolves rapidly, does not adhere to the teeth, and does not have a disturbing haptic effect in the mouth. Although the general class of coated capsules are well known in the art, it is equally well-known that there are abundant challenges remaining to develop coated capsules with specific properties. It is also well-known that small changes in ingredients and their amounts can have a substantial and unpredictable result on the properties of the shell and the interaction of the shell with the core or the shell with any coating deposited thereon. Prior to the Applicants' development of the claimed microcapsule, researchers had not successfully developed a shell-coating combination with the properties of the claimed spherical coated capsule: a large diameter, thin shelled spherical coated capsule that is stable during manufacturing and handling but that dissolves rapidly once in the mouth, does not adhere to the teeth, and does not have a disturbing mouthfeel. The Applicants were able to develop the claimed microcapsule, which successfully provides these properties, using a unexpected combination of ingredients that is neither disclosed or suggested by the cited art, whether alone or in combination.

In contrast to this problem and solution, the only disclosure in either cited reference that is even broadly related to the problem of the present invention is found in Pearce, paragraph [0088], which references "a powder to reduce tackiness." However, this passage does not pertain to the technical field of the invention, which is producing a coated seamless capsule that does not adhere to the teeth or produce an annoying haptic effect. Rather, the only portion of Pearce's disclosure even remotely related to this problem pertains to preventing adherence to machinery or adjacent materials during production or shipping. Adherent or tacky materials will adhere to surfaces of production machinery or packaging materials, thus creating unwanted residues and contamination. It is therefore necessary to prevent the material from adhering to these surfaces. This is conventionally done by adding a thin layer of powder, such as talc, to the material to reduce adherence. An example of this approach is chewing gum, which is sprinkled with white powder so that it does not adhere to the paper wrapping.

Pearce acknowledges that the soluble films disclosed therein are adherent to one another and proposes dispensers as a solution, *see* Pearce, paragraphs [0150]-[0154]. Pearce does not

suggest reformulating the film (shell) and providing a compatible coating to avoid adherence to both tissue and adjacent materials. What Pearce does disclose is that:

One problem is that the films are stacked, and sometimes become lightly adhered to one another, especially in humid environments. Even when not adhered, it can be difficult to slide the film out of the container while leaving the other films behind, because to be successful the method requires proper technique, dexterity, and involves the use of the finger which will vary in its friction characteristics from person to person and day to day, and will be seen as non-hygienic by some.

Pearce, paragraph [0150]. Thus, it is clear that Pearce's films are adherent, unlike the claimed spherical coated capsules.

The approach to solve the problem of adherence to adjacent materials or machinery does not generally have anything in common with approaches to reduce adherence to the teeth. A powder applied to avoid adherence of an adherent substance, *e.g.*, gum, to a wrapper provides a physical barrier to prevent adherence. However, once chewing commences, this physical barrier is disrupted (dissolved in many cases) and cannot prevent adherence to the teeth or other oral tissues. Thus, if Pearce would have had in mind the problem of the present invention, he would not have proposed a solution that is obviously not applicable to the problem of the present invention but only applicable to the problem of reducing adherence to machinery.

The difference between the problem solved by Pearce and the problem of the claimed spherical coated capsule is also visible when considering that the claimed spherical coated capsules solve this problem, in part, by the provision of at least one sugar or sugar-alcohol in the solid coating. This produces a shell-coating complex that prevents adherence and an annoying mouthfeel. Pearce is completely silent about a seamless coating and the amount of sugar or sugar-alcohol, which is claimed as 30 - 90 % (m/m) based on the total mass of the claimed coated spherical coated capsule. It is a distinguishing feature identified by the inventors that instead of providing more of the talc powder to reduce tackiness to machinery, the problem of the present invention is instead solved by combining the claimed seamless shell with the solid, seamless coating, having the claimed ingredients in the claimed amounts. Thus, the elements of the claimed seamless coated capsule, *e.g.*, a shell comprising gelatine and plasticizer combined with a coating comprising a specified amount of sugar or sugar-alcohol - are carefully adapted to each other to

overcome the problems of prior art. Applicants note that none of the cited references, whether alone or in combination, disclose or suggest this combination of ingredients.

The person skilled in the art is thus aware of the differences between reducing adherence to the teeth and reducing adherence to machinery. Thus, such a person would not have considered Pearce, which relates to a different field of art, for solving the problem of the present invention. Because the Pearce document does not pertain to the technical field of the invention, Applicants respectfully assert that Pearce cannot be combined with any of the cited references without improperly resorting to hindsight. Since all of the Examiner's objections rely on a combination of Pearce with other documents we believe they are not valid.

In the Office Action, claims 6-10, 13 and 17-20 were rejected under 35 U.S.C. § 103(a) as being obvious over Pearce in view of Stapler in view of at least one of U.S. Patent No. 6,770,311 issued to Alamian *et al.* (hereinafter "Alamian"), U.S. Patent No. 5,378,131 issued to Greenberg *et al.* (hereinafter "Greenberg"), and U.S. Patent No. 4,888,140 issued to Schlameus *et al.* (hereinafter "Schlameus"). Applicants now address these references.

According to the Examiner, Alamian discloses that a skilled person would contemplate the use of gelatine, fish gelatine etc. and alginate for the production of microcapsules. However, the capsules described by Alamian are explicitly said to be caviar replacements. It is well-known that caviar is sticky. Thus, when trying to produce non-sticky microcapsules, the skilled person would not have contemplated the use of the materials mentioned in the Alamian reference since he would have to believe that these materials would render the microcapsules sticking to teeth, tongue etc.

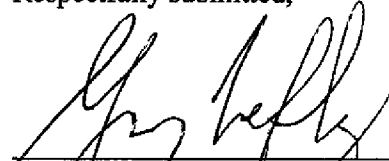
The Examiner cites Greenberg to establish that the skilled person would have contemplated using the flavours mentioned in pending claim 10 in the production of microcapsules. This document is simply not relevant because it does not effect novelty and inventiveness of pending claim 1.

Schlameus discloses a method for producing round, filled microcapsules. However, Schlameus does not disclose providing a coating on the microcapsules. In addition, Schlameus does not provide any indication regarding the stickiness properties of the microcapsules. It is thus Applicants' position that Schlameus is just general prior art and not any relevant for assessing novelty or inventiveness of the present set of claims.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,



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